BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
JONATHAN F. OLIN
Deputy Assistant Attorney General
MICHAEL S. BLUME
Director
JILL FURMAN
Deputy Director

CLINT NARVER
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, NW, Suite 6400 South
Washington, DC 20530
Tel. (202) 598-8056
Fax: (202) 514-8742
Clint.L.Narver@usdoj.gov

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. VIVACEUTICALS, INC., d/b/a REGENECA WORLDWIDE, a corporation, and MATTHEW A. NICOSIA, an individual, Defendants.	Case No.: 8:15-cv-1893 **COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent

equitable authority of this Court, to permanently enjoin VivaCeuticals, Inc., doing business as Regeneca Worldwide, a corporation, and Matthew A. Nicosia, an individual (collectively, "Defendants") from:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or U.S.C. § 342(a)(2)(C)(i);

B. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements) that are misbranded within the meaning of 21 U.S.C. § 343(a)(1);

C. Violating 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or U.S.C. § 342(a)(2)(C)(i);

D. Violating 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) that are held for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343(a)(1);

E. Violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce a new drug, as defined by 21 U.S.C. § 321(p), that is neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i); and

F. Violating 21 U.S.C. § 331(k) by causing an article of drug that is held for sale after shipment of one or more of its components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

Defendants

4. Defendant VivaCeuticals, Inc., doing business as Regeneca Worldwide, ("VivaCeuticals") is incorporated under the laws of the state of Nevada. VivaCeuticals manufactures and distributes dietary supplements and drugs. VivaCeuticals does business at 2 Park Plaza, Suite 1200, Irvine, California 92614, and 16 Technology Drive, Suite 124, Irvine, California 92618, (collectively, the "Facility"), within the jurisdiction of this Court.

5. Defendant Matthew A. Nicosia is the Chief Executive Officer of VivaCeuticals. Mr. Nicosia is the most responsible person at the firm. He has ultimate authority over all of the firm's operations, including major financial expenditures, product formulation, product release for distribution, product recalls, and the content of the firm's labeling and websites, including www.regeneca.com, www.regeneca.net, www.regeneslim.com, and www.tryslimnow.com. Defendant Nicosia performs his duties at 2 Park Plaza, Suite 1200, Irvine, California 92614, within the jurisdiction of this Court.

6. Defendants have been and are now engaged in the business of manufacturing and distributing:

A. Dietary supplements within the meaning of the Act, which defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet" that contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of them, and that "is labeled as a dietary supplement" and "is not represented for use as a conventional food or as a sole item of a meal or the diet." 21 U.S.C.

§ 321(ff). (Except for purposes of 21 U.S.C. §§ 321(g) and 350f, dietary supplements are deemed to be food under the Act. 21 U.S.C. § 321(ff)); and

B. A product that meets the definition of drug under the Act, 21 U.S.C. § 321(g)(1), in that its labeling contains claims that establish that the product is intended to cure, mitigate, treat, and/or prevent disease.

7. Defendants' products are manufactured using components shipped to California from locations outside the state, including China. Defendants distribute their products to customers in locations outside the state of California, including Florida, Iowa, and Nevada.

Defendants' Violations of the Act

Adulterated Dietary Supplements

8. The Act deems a dietary supplement to be adulterated if it is not prepared, packed, and held in conformance with current good manufacturing practice for dietary supplements ("Dietary Supplement CGMP"). 21 U.S.C. § 342(g)(1). Manufacturing according to Dietary Supplement CGMP means that the manufacturing process incorporates a set of controls in the design and production processes to assure a finished product of acceptable, predictable, and reliable quality. The Dietary Supplement CGMP regulations are set forth at 21 C.F.R. Part 111.

9. FDA inspected Defendants' Facility on July 24, August 1, 6, and 21, and September 3, 2014 ("2014 inspection"). That inspection established that the dietary supplements Defendants manufacture and distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they are prepared, packed, or held in a manner that does not conform to Dietary Supplement CGMP regulations. During the 2014 inspection, an FDA investigator documented significant deviations from Dietary Supplement CGMP regulations, which include, but are not limited to, the following:

A. Failure to establish for each component an identity specification and other specifications necessary to ensure that the finished batch of dietary supplements manufactured using the component meets its specifications for purity, strength and composition, as required by 21 C.F.R. § 111.70(b);

B. Failure to establish product specifications for the identity, purity, strength, and composition of, and limits on the types of contamination that may adulterate or may lead to adulteration of, the finished batch of dietary supplements, as required by 21 C.F.R. § 111.70(e);

C. Failure to conduct at least one appropriate test or examination to verify the identity of every component that is a dietary ingredient before such component is used in the manufacture of a dietary supplement, as required by 21 C.F.R. § 111.75(a)(1)(i);

D. Failure to determine whether component specifications that must be established in accordance with 21 C.F.R. § 111.70(b) are met before such component is used in the manufacture of a dietary supplement, as required by 21 C.F.R. § 111.75(a)(2);

E. Failure to prepare and follow a complete written master manufacturing record for each unique formulation of dietary supplement, and for each batch size, to ensure uniformity in the finished product from batch to batch, as required by 21 C.F.R. § 111.205;

F. Failure to prepare a batch production record each time a batch of dietary supplements is manufactured, as required by 21 C.F.R. § 111.255;

G. Failure to establish and follow written procedures for the responsibilities of the quality control operations set forth in 21 C.F.R. § 111.105, as required by 21 C.F.R. § 111.103;

H. Failure to establish and follow written procedures for holding and distributing operations, as required by 21 C.F.R. § 111.453, and make and

keep written procedures for holding and distributing operations, and records of product distribution, as required by 21 C.F.R. § 111.475(b);

I. Failure to establish and follow written procedures for returned dietary supplements, as required by 21 C.F.R. § 111.503; and

J. Failure to establish and follow written procedures for the review and investigation of product complaints, as required by 21 CFR § 111.553.

10. During the 2014 inspection, an FDA investigator visited Defendants' warehouse located at 16 Technology Drive, Suite 124, Irvine, California, and collected samples of RegeneSlim (Lots EX0716R17414 and 11414RE5516). FDA analyzed the samples and detected 1, 3-dimethylamylamine (DMAA) in both product lots.

11. During an investigation on August 5, 2014, at Defendants' contract packager, an FDA investigator collected samples of RegeneSlim (Lots 823230415 and EX0616R15813). FDA analyzed the samples and detected DMAA in both product lots.

12. In May 2014, FDA made an undercover purchase of RegeneSlim (Lot EX0616R15814) from one of Defendants' websites, www.tryslimnow.com. FDA's analysis detected the presence of DMAA in this product lot.

13. Because RegeneSlim contains DMAA or its chemical equivalents (collectively referred to as DMAA), the product is adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i) in that it contains a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a).

14. Under 21 U.S.C. § 321(s), a food additive is:

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component … of any food … if such substance is not generally recognized, among experts qualified by scientific

> training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—
> (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
> (2) a pesticide chemical; or
> (3) a color additive; or
> (4) any substance used in accordance with a sanction or approval granted prior to [September 6, 1958] pursuant to this Act, the Poultry Products Inspection Act … or the Meat Inspection Act …; or
> (5) a new animal drug; or
> (6) an ingredient described in [21 U.S.C. § 321(ff)] in, or intended for use in, a dietary supplement.

Thus, if a substance that is added to food is not generally recognized as safe, it meets the food additive definition unless it falls within one of the exceptions set forth in 21 U.S.C. § 321(s)(1)-(6).

15. FDA's regulations state that "[g]eneral recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food," and may be based on "scientific procedures" or, "in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food." 21 C.F.R. § 170.30(a).

A. General recognition of safety based on scientific procedures "require[s] the same quantity and quality of scientific evidence as is required to

obtain approval of a food additive regulation for the ingredient" and "shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information." 21 C.F.R. § 170.30(b).

B. General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation but "shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information." 21 C.F.R. § 170.30(c)(1).

C. "An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety *only* through scientific procedures." 21 C.F.R. § 170.30(c)(1) (emphasis added).

16. FDA is not aware of any evidence to show that DMAA was used in food prior to 1958. Therefore, DMAA may achieve general recognition of safety only through scientific procedures. *See* 21 C.F.R. § 170.30(c)(1).

17. There are no adequate studies in the published scientific literature to show that DMAA is safe for use in food. Therefore, qualified experts cannot come to a consensus of opinion concerning DMAA's safe use in food and, thus, DMAA is not generally recognized as safe under the conditions of its intended use.

18. DMAA does not fall within any exception from the food additive definition. *See* 21 U.S.C. § 321(s)(1)-(6). Therefore, DMAA is a food additive.

19. Under 21 U.S.C. § 348(a):

> A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of [21 U.S.C. § 342(a)(2)(C)], unless—

> (1) it and its use or intended use conform to the terms of an exemption [for investigational use] which is in effect pursuant to [21 U.S.C. § 348(j)]; [or]
>
> (2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used[.]

20. DMAA is not the subject of a regulation prescribing the conditions under which it may be safely used or an exemption for investigational use. Therefore, DMAA is a food additive that is deemed unsafe under 21 U.S.C. § 348(a).

21. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held under conditions that do not meet Dietary Supplement CGMP regulations, 21 C.F.R. Part 111.

22. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i) in that they contain a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a).

23. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

24. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that are held for sale after shipment of one or more of their

components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i).

Misbranded Dietary Supplements

25. A food is misbranded if its "labeling is false or misleading in any particular." 21 U.S.C. § 343(a)(1). The Act provides that, "in determining whether the labeling . . . is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling." 21 U.S.C. § 321(n).

26. As noted in paragraphs 10-12 above, analytical testing of RegeneSlim detected DMAA in the product.

27. DMAA has the potential to pose serious adverse health risks in that it may elevate blood pressure which, in turn, may stress the heart, causing shortness of breath, tightening of the chest, and possibly a heart attack.

28. The labeling for RegeneSlim is false or misleading because it does not declare that it contains DMAA or reveal the consequences that may result from using a product containing this ingredient. Therefore, RegeneSlim is misbranded within the meaning of 21 U.S.C. § 343(a)(1).

29. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (dietary supplements) that are misbranded within the meaning of 21 U.S.C. § 343(a)(1).

30. Defendants violate 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) that are held for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343(a)(1);

Unapproved New Drugs

31. The Act's definition of drug includes products that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. 21 U.S.C. § 321(g)(1)(B).

32. A drug that is a "new drug" within the meaning of the Act is prohibited from being introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application or abbreviated new drug application for that drug, or the drug is exempt from approval under an investigational new drug application. *See* 21 U.S.C. §§ 355(a), (b), (i), and (j).

33. Because a product's intended use determines whether it is a drug under the Act, a product that falls within the Act's dietary supplement definition may also meet the Act's drug definition if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. *See* 21 U.S.C. § 321(ff).

34. Defendants cause their RegeneSlim product to be a drug under the Act because they make claims that the product is intended to cure, mitigate, treat, or prevent diseases ("disease claims").

35. FDA's review of Defendants' websites, www.regeneslim.com and www.tryslimnow.com, on April 21, 2015, documented that Defendants state that RegeneSlim contains ChromeMate®, which according their websites is a "unique patented form of oxygen-coordinated niacin-bound chromium found to be 18-times more bio-active than other forms of niacin-bound chromium that have been tested." Defendants' websites contained the following claims for the ingredient, ChromeMate®:

> Clinical studies** have shown that ChromeMate® lowers serum cholesterol and improves HDL (good) cholesterol levels, lowers blood pressure, reduces body weight, . . . and promotes proper insulin function in the body… It also increases insulin…

The claims, "lowers serum cholesterol," "lowers blood pressure," and "promotes proper insulin function…[and] increases insulin," demonstrate that Defendants intend that the ChromeMate®-containing RegeneSlim cures, mitigates, treats, or prevents high cholesterol, high blood pressure, and diabetes, respectively.

36. A drug is a "new drug" if "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective" ("GRAS/E"), it must have substantial evidence of safety and effectiveness. *See* 21 U.S.C. § 355(d).

37. Defendants' RegeneSlim lacks substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations to show that RegeneSlim is effective for any use and, therefore, qualified experts cannot come to a consensus of opinion concerning the effectiveness of this product. Thus, RegeneSlim is not GRAS/E.

38. Because Defendants' RegeneSlim is not GRAS/E, it is a new drug.

39. FDA searched its records and found no new drug application, abbreviated new drug application, or investigational new drug application for RegeneSlim. Therefore, RegeneSlim is an unapproved new drug within the meaning of the Act, 21 U.S.C. § 355(a).

40. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce a new drug, as defined by 21 U.S.C. § 321(p), that is neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i).

Misbranded Drugs

41. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and it does not fall within a regulatory exemption from that requirement. "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5(a).

42. By definition, a drug that is also a prescription drug cannot have adequate instructions for lay use. 21 U.S.C. § 353 (b)(1)(A) (requiring a drug to be dispensed by prescription that, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug").

43. Drugs that are unapproved are not exempt from the requirement for adequate directions for use. *See* 21 C.F.R. §§ 201.100(c)(2), 201.115.

44. It is not possible to write adequate directions for use for Defendants' RegeneSlim because such directions -- including dosages, indications, contraindications, warnings, side effects, and necessary collateral measures -- are premised on animal and clinical data derived from extensive, scientifically controlled testing and reviewed by FDA during the approval process. As noted in paragraph 37 above, there are no well-controlled clinical test data for RegeneSlim.

45. In addition, because of the purposes for which it is intended and/or the potential for serious adverse effects, RegeneSlim is a prescription drug, which, as a matter of law, cannot meet the requirement for "adequate directions for use." *See* U.S.C. § 352(f)(1); 21 C.F.R. § 201.5(a).

46. Defendants' RegeneSlim is misbranded within the meaning of 21 U.S.C. § 352(f)(1) because its labeling fails to bear adequate directions for use.

47. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

Warnings and Previous Violations

48. Defendants have been warned about their ongoing violations. At the close of the 2014 inspection, an FDA investigator issued a List of Inspectional Observations ("Form FDA-483") to Defendant Nicosia, and discussed each of the observed Dietary Supplement CGMP deviations with him. The FDA investigator also informed Defendant Nicosia about the laboratory analyses that detected an undeclared substance, namely DMAA, in multiple lots of RegeneSlim (Lots EX0716R17414, 11414RE5516, 823230415, EX0616R15813, and EX0616R15814), and that DMAA cannot be used as an ingredient in dietary supplements.

49. Defendants received a Warning Letter, dated August 28, 2012, from FDA notifying them that the use of DMAA in RegeneSlim causes the product to be adulterated. The 2012 Warning Letter cautioned Defendants about the potential health hazards associated with DMAA, and emphasized that Defendants' failure to immediately cease distribution of RegeneSlim and any other products that contain DMAA could result in enforcement actions, such as injunction.

50. Defendants have a history of adding undeclared substances, including as active pharmaceutical ingredients, to products they market as dietary supplements. During an inspection in February 2012, an FDA investigator informed Defendants that the agency's laboratory analysis of Defendants' RegenArouse product (Lot 130100) revealed the presence of tadalafil, the active ingredient in Cialis. In addition, FDA's laboratory analyses of samples collected during the 2012 inspection confirmed that multiple lots of RegenErect (Lots 120126, 120128, 120129) also contained tadalafil.

51. FDA previously warned Defendants about the use of undeclared active pharmaceutical ingredients in their products and labeling claims that cause their products to meet the Act's drug definition. FDA issued a Warning Letter, dated May 25, 2011, to Defendants that stated: FDA's analyses identified sulfoaildenafil (an analog of sildenafil, the active ingredient in Viagra) in multiple lots of RegenErect; Defendants' claims cause RegenErect to be a drug within the meaning of the Act because the product is intended to cure, treat, or prevent diseases and/or affect the structure or function of the body; and, the product is a misbranded and an unapproved new drug. The 2011 Warning Letter emphasized the serious nature of the violations and advised Defendants that RegenErect could cause harm to consumers. As described in the letter, Defendants were warned that they may be subject to legal action, including an injunction, for failure to take prompt action to correct the violations.

52. Defendants have promised corrective actions, but they have consistently failed to achieve compliance with the law. Following the 2014 inspection, Defendant Nicosia submitted a written response, dated September 20, 2014, but failed to adequately address several significant Dietary Supplement CGMP deficiencies documented on the Form FDA-483. In response to FDA's Warning Letters issued in 2011 and 2012, Defendant Nicosia made additional promises and stated that Defendants would no longer distribute products that contained PDE-5 inhibitors (e.g., active pharmaceutical ingredients in Viagra, Cialis, and Levitra) or DMAA. Despite their promises, however, Defendants subsequently distributed products that contained PDE-5 inhibitors or DMAA, as confirmed by FDA's laboratory analyses.

53. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above. WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, cease receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing articles of dietary supplement and/or articles of drug, unless and until:

A. Defendants' facilities, methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are established, operated, and administered in conformity with Dietary Supplement CGMP and the Act, in a manner that has been found acceptable to FDA;

B. Defendants have methods, processes, and controls that are adequate to ensure that none of the dietary supplements that Defendants receive, manufacture, prepare, pack, repack, label, hold, or distribute contain a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a), in a manner that has been found acceptable to FDA;

C. Defendants' dietary supplement labeling complies with 21 U.S.C. § 343(a)(1) and applicable regulations, in a manner acceptable to FDA; and

D. Defendants' labeling does not contain claims that cause any dietary supplement that Defendants manufacture, prepare, pack, label, hold, or distribute to meet the Act's definition of a drug, 21 U.S.C. § 321(g)(1)(B), unless and until the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), and (j).

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently

restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (including but not limited to dietary supplements and their components) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1);

B. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (including but not limited to dietary supplements and their components) that are adulterated within the meaning of U.S.C. § 342(a)(2)(C)(i);

C. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (including but not limited to dietary supplements and their components) that are misbranded within the meaning of 21 U.S.C. § 343(a)(1);

D. Violating 21 U.S.C. § 331(k) by causing articles of food (including but not limited to dietary supplements and their components) that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1);

E. Violating 21 U.S.C. § 331(k) by causing articles of food (including but not limited to dietary supplements and their components) that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of U.S.C. § 342(a)(2)(C)(i);

F. Violating 21 U.S.C. § 331(k) by causing articles of food (including but not limited to dietary supplements and their components) that are

held for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of U.S.C. § 343(a)(1);

G. Violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i); and

H. Violating 21 U.S.C. § 331(k) by causing articles of drug held for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, preparing, packing, labeling, holding, and distribution of all of Defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

DATED this 16th day of November, 2015.

Respectfully submitted,

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
JONATHAN F. OLIN
Deputy Assistant Attorney General
MICHAEL S. BLUME
Director
JILL FURMAN
Deputy Director

By: /s/ Clint Narver
Clint Narver
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
(202) 598-8056
Clint.L.Narver@USDOJ.gov

OF COUNSEL:
WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC

Deputy Chief Counsel for Litigation

CLAUDIA J. ZUCKERMAN
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 31, Room 4550
Silver Spring, MD 20993-0002
301-796-8609